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RICHARD W. WIEKING  
CLERK, U.S. DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA  
(SAN FRANCISCO DIVISION)

**In re: Bextra and Celebrex Marketing Sales  
Practices and Product Liability Litigation**

**MDL No. 1699**

**District Judge: Charles R. Breyer  
Magistrate:**

**MARIE A. TEAL**, individually,

Plaintiff,

v.

**PFIZER, INC., PHARMACIA CORP., and  
G.D. SEARLE, LLC, (FKA G.D. SEARLE  
& CO.),**

Defendants.

**CV 08**

Case No. \_\_\_\_\_

**CIVIL COMPLAINT**

**JURY TRIAL DEMANDED**

**CRB  
1008**

PLAINTIFF, **MARIE A. TEAL**, individually, pursuant to Pretrial Order 12, by  
and through counsel and pursuant to applicable law, brings this action against Defendants  
**PFIZER, INC., PHARMACIA CORP., and G.D. SEARLE & CO.** (hereafter "Defendants") and  
alleges as follows:

1       **I. PARTIES**

2               1.       This is an action for damages arising from Defendants' design,  
3       manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe  
4       medication Valdecocix, trade name BEXTRA® ("Bextra").

5               2.       Plaintiff is and was at all relevant times an adult resident citizen of New  
6       Mexico, residing at the address in the City, State and County identified in Section IV(A) herein.  
7       ("Named Plaintiff's Home District"). The Named Plaintiff's Home District is proper for purposes  
8       of remand, transfer, and venue.

9               3.       Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its  
10       principal place of business in New York. In 2003, Pfizer acquired Pharmacia for nearly  
11       \$60 billion. At all relevant times Pfizer and/or its predecessors in interest were engaged in the  
12       business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and  
13       selling the drug Valdecocix, under the trade name Bextra in Named Plaintiff's Home District and  
14       nationwide.

15              4.       Defendant Searle ("Searle") is a Delaware corporation with its principal  
16       place of business in Illinois. At all relevant times, Searle has been engaged in the business of  
17       marketing and selling Bextra nationwide and in Named Plaintiff's Home District. Searle is a  
18       subsidiary of Pfizer, acting as its agent and alter ego in all matters alleged within this Complaint.

19              5.       Defendant Pharmacia ("Pharmacia") is a Delaware corporation with its  
20       principal place of business in New Jersey. At all relevant times, Pharmacia, and its predecessors  
21       in interest have been engaged in the business of designing, testing, manufacturing, packaging,  
22       marketing, distributing, promoting, and selling Bextra nationwide and in Named Plaintiff's Home  
23       District.

24       **II. JURISDICTION AND VENUE**

25              6.       This is an action for damages, which exceeds seventy-five thousand dollars  
26       (\$75,000.00).

27              7.       There is complete diversity of citizenship between the Plaintiff and  
28       Defendants. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A.

1 § 1332 (diversity jurisdiction) because the amount in controversy exceeds \$75,000.00, and  
2 because there is complete diversity of citizenship between Plaintiff and Defendants.

3 8. This action is being filed in the Northern District of California Pursuant to  
4 MDL 1699, Pretrial Order No. 2. However, venue is proper in the Named Plaintiff's Home  
5 District pursuant to Pretrial Order 12 and 28 U.S.C.A. § 1391. Defendants marketed, advertised  
6 and distributed the dangerous product in the Named Plaintiff's Home District, thereby receiving  
7 substantial financial benefit and profits the dangerous product in the Name Plaintiff's Home  
8 District, and reside in the Named Plaintiff's Home District under 28 U.S.C.A. § 1391(c), such that  
9 venue is proper.

10 9. At all relevant times herein, Defendants were in the business of designing,  
11 manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and  
12 selling their product, Bextra. Defendants at all times relevant hereto designed, developed,  
13 manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce  
14 (including Named Plaintiff's Home District) the aforementioned prescription drug. Defendants  
15 do substantial business in the State of Named Plaintiff's Home District, advertise in the district,  
16 receive substantial compensation and profits from sales of Bextra in the District, and made  
17 material omissions and misrepresentations and breaches of warranties in the District so as to  
18 subject them to *in personam* jurisdiction in the District. In engaging in the conduct alleged herein  
19 each defendant acted as the agent for each of the other defendants, or those defendant's  
20 predecessors in interest.

### 21 **III. INTERDISTRICT ASSIGNMENT**

22 10. Assignment to the San Francisco Division is proper as this action is related  
23 to *In Re: Bextra and Celebrex Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to  
24 the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6,  
25 2005.

1       **IV. FACTUAL BACKGROUND**

2           **A. Facts Regarding Plaintiff**

3           11. Plaintiff, **MARIE A. TEAL**, is an adult resident citizen of New Mexico,  
4 residing at 5700 Mariola Place, NE, Albuquerque, NM 87109 in Bernalillo County. For purposes  
5 of remand, transfer and venue, this is in the District of New Mexico. **MARIE A. TEAL** was  
6 prescribed, and began taking, Bextra during 2004. As a direct and proximate result of using  
7 Bextra, Plaintiff suffered severe cardiovascular injuries. Specifically, on or about January 29,  
8 2005 Plaintiff suffered a cardiovascular injuries including a heart attack which caused Plaintiff's  
9 damages and injuries set forth herein.

10          12. Unaware of the risks presented by Bextra, or that Bextra was the cause of  
11 the respective injuries, Plaintiff continued to take Bextra until the date of her adverse  
12 cardiovascular event.

13          13. Plaintiff and Plaintiff's healthcare providers were at the time of Plaintiff's  
14 adverse cardiovascular event unaware—and could not have reasonably known or have learned  
15 through reasonable diligence—that such injury directly resulted from Defendants' negligence and  
16 otherwise culpable acts, omissions, and misrepresentations or from Plaintiff's ingestion of Bextra.

17          14. Plaintiff used Bextra in a proper and reasonably foreseeable manner and  
18 used it in a condition that was substantially the same as the condition in which it was  
19 manufactured and sold.

20          15. Plaintiff would not have used Bextra had Defendants properly disclosed the  
21 risks associated with the drug.

22               WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
23 compensatory damages, and exemplary and punitive damages together with interest, the costs of  
24 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

25           **B. Facts Regarding Bextra**

26          16. Bextra is one of a class of pain medications called non-steroidal anti-  
27 inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade  
28 name Advil) are examples of well-known NSAIDs.



1           17.     NSAIDs reduce pain by blocking the body's production of pain  
2 transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX  
3 enzymes—COX-1 and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and  
4 COX-2 enzymes.

5           18.     In addition to decreasing inflammation, the prostaglandins that are  
6 supported by COX-1 enzymes are involved in the production of gastric mucus; this protects the  
7 stomach wall from the hydrochloric acid present in the stomach. It is generally accepted in the  
8 medical community that by blocking the COX-1 enzyme, the body's ability to protect gastric  
9 tissue is hampered and as a result can cause harmful gastrointestinal side effects, including  
10 stomach ulceration and bleeding. Prostaglandin I<sub>2</sub> is the predominant cyclooxygenase product in  
11 endothelium, inhibiting platelet aggregation (preventing clot formation), causing vasodilation,  
12 and preventing the proliferation of vascular smooth muscle. Whereas older NSAIDs inhibit  
13 Thromboxane A<sub>2</sub> and Prostaglandin I<sub>2</sub>, the COX-2 inhibitors leave Thromboxane A<sub>2</sub> unaffected.  
14 Thromboxane A<sub>2</sub> is a potent platelet aggregator and vasoconstrictor which is synthesized by  
15 platelets. Therefore, while the older NSAIDs suppress platelet aggregation and vasoconstriction,  
16 the COX-2 inhibitors support it. Traditional NSAIDs like aspirin reduce pain/inflammation and  
17 therefore pain by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be  
18 expected, traditional NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do  
19 not cause blood clots, rather they actually reduce the risk of clots and help protect heart function.

20           19.     Defendants and other pharmaceutical companies set out to remedy these  
21 ulcer and bleeding problems suffered by some NSAID users by developing "selective" inhibitors  
22 that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of  
23 gastric tissue while still reducing inflammation.

24           20.     In making this decision, Defendants and their predecessors in interest either  
25 intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2  
26 inhibition lowers prostacyclin levels and causes thromboxane A<sub>2</sub> to be uninhibited, causing blood  
27 clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke,  
28 unstable angina. The vasoconstriction and fluid retention cause the hypertension.

1           21. The defendants launched Celebrex, the first of the three major COX-2  
2 inhibitor drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and  
3 consumers of the superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In  
4 May, 1999, Merck & Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.

5           22. Seeking increased market share in this extremely lucrative market,  
6 Defendants, and their predecessors in interest, also sought approval of a “second generation”  
7 selective COX-2 inhibitor and filed for FDA approval of Bextra on January 16, 2001 for the  
8 (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief  
9 of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

10           23. The FDA granted approval of the new drug on November 16, 2001, for two  
11 particular uses: (i) treatment of primary dysmenorrhea and (ii) relief for the signs and symptoms  
12 of osteoarthritis and rheumatoid arthritis.

13           24. The FDA did not grant approval to market and promote Bextra for the  
14 management or prevention of acute pain.

15           25. The FDA did not grant approval to promote Bextra as more effective than  
16 other NSAIDs in preventing clinically serious gastrointestinal events such as perforations, ulcers  
17 or gastric bleeding.

18           26. Even without a label that allowed Defendants to legitimately claim superior  
19 safety, when Defendants, and their predecessors-in-interest, began marketing Bextra in early  
20 2002, Defendants and their representatives and agents misrepresented the safety profile of Bextra  
21 to consumers, the medical community, healthcare providers, and third party payors. Defendants  
22 proceeded to promote, market, sell, and distribute Bextra as a much safer and more effective pain  
23 reliever than other NSAIDs, such as aspirin, naproxen, and ibuprofen.

24           **C. Facts Regarding Bextra’s Safety**

25           27. The potential for cardiovascular risk of selective COX-2 inhibitors was  
26 known to Defendants long before the FDA granted market approval for Bextra. By 1997, and  
27 prior to the submission of the New Drug Application (the “NDA”) for Bextra, Defendants were  
28 aware that, by inhibiting COX-2, Bextra altered the homeostatic balance between prostacyclin

1 synthesis and thromboxane and thereby, increased the prothrombotic effects of the drugs, causing  
2 blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, *Risk of Cardiovascular*  
3 *Events Associated with Selective Cox-2 Inhibitors*, *JAMA*, August 22, 2001 at 954. Although all  
4 COX-2 inhibitors have this mechanism of action, Bextra was the most selective COX-2 inhibitor  
5 proposed for approval. Accordingly, it had the greatest potential to cause adverse cardiovascular  
6 and cerebrovascular events.

7 28. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of  
8 Pennsylvania, reported in an editorial published in *The New England Journal of Medicine* on  
9 October 21, 2004, that it was known as early as 1999 that selective COX-2 inhibitors, such as  
10 Bextra, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet  
11 aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.

12 29. Nevertheless, the Defendants submitted an NDA to the FDA for Bextra,  
13 omitting information about the extent of the risks associated with Bextra. Without a complete  
14 picture of the potential hazards associated with the drug, the FDA approved Bextra on or about  
15 November 16, 2001.

16 30. Based on the studies performed on Bextra, other COX-2 inhibitors, and  
17 basic research on this type of selective inhibitor which had been widely conducted, Defendants  
18 knew when Bextra was being developed and tested that selective COX-2 inhibitors posed serious  
19 cardiovascular risks for anyone who took them, and presented a specific additional threat to  
20 anyone with existing heart disease or cardiovascular risk factors.

21 31. Studies show that selective COX-2 inhibitors, including Bextra, decrease  
22 blood levels of a prostacyclin. When those levels fall, the arteries are more vulnerable to clotting,  
23 high blood pressure, heart attack, and stroke.

24 32. The defendants marketed Bextra in the United States for three years (April,  
25 2002 – April 7, 2004). During that time the FDA forced the defendants to strengthen the warning  
26 label several times. The enhanced warnings followed in the wake of the results of additional  
27 cardiovascular studies performed by Defendants, as well as numerous complaints to the FDA  
28 regarding various adverse events.



1           33. Prior to strengthening the warning for Bextra, Defendants had knowledge  
2 of the coronary and cardiovascular safety risks of Bextra from several studies. *See e.g., Otto,*  
3 *E.O., Efficacy and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in*  
4 *Patients Undergoing Coronary Artery Bypass Surgery, The Journal of Thoracic and*  
5 *Cardiovascular Surgery*, June 2003 at 1481.

6           34. Even Defendants' own (and Pfizer funded) post- drug approval meta-  
7 analysis study (first presented on March 31, 2003 and again on May 15, 2003) included this data  
8 showing an increased cardiovascular risk in patients treated with Bextra after undergoing  
9 coronary artery bypass graft surgery. Observed events included heart attack, stroke, and blood  
10 clots in the legs and lungs. The results were particularly relevant and striking as each of the study  
11 participants who was a post-bypass surgery patient was taking anti-clotting agents at the time  
12 their exposure to Bextra was being tracked.

13           35. In mid-January 2005, a peer-reviewed paper from the University of  
14 Pennsylvania found that in patients having heart bypass surgery, those who took Bextra in the  
15 intravenous form, parecoxib, as opposed to a placebo, were three times more likely to have a  
16 heart attack or stroke.

17           36. Despite years of studies on selective COX-2 inhibitors, as well as the  
18 disturbing new studies specifically analyzing the risks of Bextra, Defendants failed to take any  
19 action to protect the health and welfare of patients, but instead, continued to promote the drug for  
20 sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis  
21 Drug Advisory Committee meetings.

22           37. On April 7, 2005, the FDA finally insisted that Defendants "voluntarily  
23 withdraw" Bextra from the U.S. market, stating:

24           ... the Agency has concluded that the overall risk versus benefit  
25 profile of Bextra is unfavorable. This conclusion is based on the  
26 potential increased risk for serious cardiovascular (CV) adverse  
27 events, which appears to be a class effect of non-steroidal anti-  
28 inflammatory drugs (NSAIDs) (excluding aspirin) ... and the fact  
that Bextra has not been shown to offer any unique advantage over  
the other available NSAIDs. (FDA Alert for Healthcare  
Professionals, April 7, 2005.)



1 38. Continuing, the FDA noted:

2 Bextra has been demonstrated to be associated with an increased  
3 risk of serious adverse CV events in two short-term trials in patients  
4 immediately post-operative from coronary artery bypass graft  
5 (CABG) surgery . . . . FDA has concluded that it is reasonable to  
6 extrapolate the adverse CV risk information for Bextra from the  
7 short-term CABG trials to chronic use given the fact that other  
8 COX-2 selective NSAIDs have been shown in long-term controlled  
9 clinical trials to be associated with an increased risk of serious  
10 adverse CV events (e.g., death, MI, stroke), and the well described  
11 risk of serious, and often life-threatening gastrointestinal  
12 bleeding . . . . To date, there have been no studies that demonstrate  
13 an advantage of Bextra over other NSAIDs that might offset the  
14 concern about the serous skin risks, such as studies that show a GI  
15 safety benefit, better efficacy compared to other products, or  
16 efficacy in a setting of patients who are refractory to treatment with  
17 other products.”

18 39. Dr. Garret A. Fitzgerald, cardiologist and pharmacologist at the University  
19 of Pennsylvania, presented the preliminary results of his Bextra study at the American Heart  
20 Association meeting in New Orleans, Louisiana. His study, containing 12 trials including 5,930  
21 patients, found 2.19 times the number of strokes among patients given Bextra. *Named Plaintiff's*  
22 *Home District Times*, Nov. 10, 2004.

23 40. Instead of studying Bextra prior to its market launch, the Defendants  
24 simply relied upon data and information gathered from Celebrex trials and studies. The Celebrex  
25 data put Pfizer on notice that Cox-2 NSAIDs are, at the very least, associated with a  
26 disproportionately increased number of adverse cardiovascular events. Taking the results from  
27 the Celebrex trials in conjunction with the available medical literature; the Defendants knew  
28 about the increased incidence and association between Bextra and the potentially life-threatening  
dangers it could cause.

41. The Named Plaintiff's Home District Times uncovered the truth about the  
inadequate studies by interviewing Pfizer researcher Dr. Feczko - Pfizer's president for  
worldwide development.

Over all, Pfizer has performed much less research on Bextra than  
on Celebrex, Dr. Feczko said. Most of the company's studies of  
Bextra have been short term, with many lasting only two weeks.  
As a result, Pfizer has less data to support its contention that Bextra  
is safe , he said.

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Dr. Feczko of Pfizer explained that the company felt it was not as important to study Bextra extensively because the company believed that the drug was similar to Celebrex.

*The Named Plaintiff's Home District Times*, February 5, 2005.

42. The Celebrex data relied upon by the Defendants was not adequate. On July 23, 2005, the New England Journal of Medicine published the results of its investigative research noting: "Most data on the cardiovascular risks associated with celecoxib have come from observational studies or short-term randomized trials." N. ENG. J. MED. 352;25 at 2649.

43. On December 23, 2004, three (3) researchers from the well-respected Vanderbilt University published an article in the New England Journal of Medicine. The doctors wrote: "To protect the safety of the public, we write to recommend that clinicians stop prescribing Valdecoxib (Bextra) except in extraordinary circumstances." N. ENG. J. MED. 351;26. The authors cite to two (2) recent studies "which showed a 3-fold increase in serious cardiovascular injuries in patients receiving Valdecoxib after coronary-artery bypass grafting." Later, on February 17, 2005, the New England Journal of Medicine published the results of a study conducted by eight (8) doctors with similarly alarming results. N. ENG. J. MED. 2005;352.

44. In January 2005, Drs. Fitzgerald, Furberg and Psaty published an editorial in *Circulation*, the official journal of the American Heart Association. This editorial was based on a meta-analysis of two (2) clinical studies, and discusses the association between intravenous administration of an identical drug, and oral administration of Bextra. All three doctors found a "3-fold higher risk of cardiovascular injuries with the drug than with a placebo." *Cir.* 2005; 111:249.

45. The scientific data available during and after Bextra's approval process made clear to Defendants that their formulation of Bextra would cause a higher risk of blood clots, stroke and/or myocardial infarctions among Bextra consumers, alerting them to the need to do additional and adequate safety studies.

46. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining Defendants' failure to have conducted the necessary trials before

1 marketing to humans “ . . . it is mandatory to conduct a trial specifically assessing cardiovascular  
2 risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with  
3 established coronary artery disease, who frequently have coexisting osteoarthritis requiring  
4 medication and have the highest risk of further cardiovascular events.”

5 47. Dr. Topol was also the author on the study published in August 2001 in  
6 JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in  
7 persons who used COX-2 inhibitors.

8 48. Based upon readily available scientific data, Defendants knew, or should  
9 have known, that their pre-approval testing of Bextra did not adequately represent the cross-  
10 section of individuals who were intended consumers and therefore, likely to take Bextra.  
11 Therefore, Defendants’ testing and studies were grossly inadequate. *See, e.g.*, PDR entry for  
12 Bextra (noting that: “Platelets: In four clinical studies with young and elderly ( $\geq 65$  years)  
13 subjects, single and multiple doses up to 7 day mg BID had not effect on platelet aggregation”).

14 49. Had Defendants done adequate testing prior to approval and “market  
15 launch,” rather than the extremely short duration studies done on the small size patient base that  
16 was actually done) Pharmacia and Searle’s scientific data would have revealed significant  
17 increases in incidence of strokes and myocardial infarctions among the intended and targeted  
18 population of Bextra consumers. Adequate testing would have shown that Bextra possessed  
19 serious side effects. Defendants should have taken appropriate measures to ensure that their  
20 defectively designed product would not be placed in the stream of commerce and/or should have  
21 provided full and proper warnings accurately and fully reflecting the scope and severity of  
22 symptoms of those side effects should have been made.

23 50. In fact, post-market approval data did reveal increased risks of clotting,  
24 stroke and myocardial infarction, but Defendants intentionally suppressed this information in  
25 order for them to gain significant profits from continued Bextra sales.

26 51. Defendants’ failure to conduct adequate testing and/or additional testing  
27 prior to “market launch” was based upon their desire to generate maximum financial gains for  
28 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2

1 inhibitor market. At the time Defendants manufactured, advertising, and distributed Bextra to  
2 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding  
3 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants  
4 knew that if such increased risks were disclosed, consumers would not purchase Bextra, but  
5 instead would purchase other cheaper and safer NSAIDs.

6 **D. Facts Regarding Defendants' Marketing and Sale of Bextra**

7 52. The defendants rushed Bextra to the market in an effort to regain Cox-2  
8 market share. In response to the introduction of Vioxx, and without performing adequate  
9 research, the Defendants hastily introduced their own more selective Cox-2 inhibitor, Bextra, to  
10 the market. In doing so, Pfizer, admittedly, relied upon problematic research results from its  
11 study of Celebrex.

12 53. Pfizer stuck to its original plan – focus on marketing and avoid studying  
13 Bextra. Thus, it was reported: “The positioning for Bextra began more than a year and a half  
14 before it hit the market. Pharmacia conducted research about the arthritis market to examine gaps  
15 in treatment, said Sylvia McBrinn, Pharmacia’s Vice President for global marketing for Bextra.”<sup>1</sup>  
16 Bextra’s marketing research was conducted over a year and a half, while science took a backseat,  
17 with one small study for Bextra lasting not even one year and the rest lasting only weeks in  
18 duration.

19 54. At all times relevant herein, Defendants engaged in a marketing campaign  
20 with the intent that consumers would perceive Bextra as a safer and better drug than its other  
21 NSAIDs and, therefore, purchase Bextra.

22 55. Such an ineffective and unreasonably dangerous drug could only be widely  
23 prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the  
24 Defendants’ marketing campaign was fraudulent and misleading. But for fraudulent and  
25 misleading advertising, consumers would not have purchased Bextra, a more costly prescriptive  
26 drug that was not effective for its intended purposes.

27  
28 <sup>1</sup> *New Jersey Record*, North Jersey Media Group, Inc., April 14, 2002.



1           56. On January 10, 2005 the FDA issued Pfizer a written reprimand for its  
2 promotional activities. The reprimand reads: "These five promotional pieces [3 Celebrex and 2  
3 Bextra] variously: omit material facts ... and make misleading safety, unsubstantiated superiority,  
4 and unsubstantiated effectiveness claims." This was not the Defendants first offense related to its  
5 Cox-2 inhibitors. The FDA also reprimanded Pfizer on October 6, 1999 noting: "DDMAC has  
6 reviewed these promotional pieces and has determined that they are false or misleading because  
7 they contain unsubstantiated comparative claims, misrepresentations of Celebrex's safety profile,  
8 and are lacking in fair balance."

9           57. Bextra was never approved for the treatment of acute pain. Without such  
10 approval, Pfizer was prohibited from marketing Bextra for such an indication. Nevertheless, in  
11 May of 2002, Pfizer issued a press release announcing the publication of a study in the Journal of  
12 the American Dental Ass'n (JADA) concluding that Bextra is effective in the treatment of acute  
13 pain associated with dental surgery. Interestingly, the dental study was sponsored by the  
14 defendants and three of the five authors were employees of Pharmacia.

15           58. Essentially, Pfizer was attempting to circumvent the FDA by promoting a  
16 study it funded and authored for an unapproved use. Once the results were published, Pfizer's  
17 aggressive promotional campaign continued. Pfizer issued a press release touting Bextra's  
18 efficacy for the treatment of acute pain. After the press release, Dr. Steve Geis, Group Vice  
19 President of Clinical Research was reported to have said the following: "Post-surgical pain can be  
20 under-managed and cause patients tremendous discomfort. ... This investigational study suggests  
21 that Bextra may offer promise in acute pain management and further study is required."<sup>2</sup>

22           59. Defendants widely and successfully marketed Bextra throughout the  
23 United States by, among other things, conducting promotional campaigns that misrepresented the  
24 efficacy of Bextra in order to induce a widespread use and consumption. Bextra was represented  
25 to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made  
26 misrepresentations by means of media advertisements, and statements contained in sales literature  
27 provided to Plaintiff's prescribing physicians.

28  
<sup>2</sup> Press Release: docguide.com March 25, 2002.

1           60.     Despite knowledge of the dangers presented by Bextra, Defendants and  
2 Defendants' predecessors in interest, through their officers, directors and managing agents for the  
3 purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy  
4 the known defects of Defendants' product, Bextra, and failed to warn the public, including  
5 Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product,  
6 Bextra. Defendants and their officers, agents and managers intentionally proceeded with the  
7 inadequate safety testing, and then the manufacturing, sale and marketing of Defendants' product,  
8 Bextra, knowing that persons would be exposed to serious potential danger, in order to advance  
9 their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a  
10 conscious disregard for the safety of the public and particularly of Plaintiff.

11           61.     In an elaborate and sophisticated manner, Defendants aggressively  
12 marketed Bextra directly to consumers and medical professionals (including physicians and  
13 leading medical scholars) in order to leverage pressure on third party payors, medical care  
14 organizations, and large institutional buyers (*e.g.*, hospitals) to include Bextra on their  
15 formularies. Faced with the increased demand for the drug by consumers and health care  
16 professionals that resulted from Defendants' successful advertising and marketing blitz, third  
17 party payors were compelled to add Bextra to their formularies. Defendants' marketing campaign  
18 specifically targeted third party payors, physicians, and consumers, and was designed to convince  
19 them of both the therapeutic and economic value of Bextra.

20           62.     Defendants represented that Bextra was similar to ibuprofen and naproxen  
21 but was superior because it lacked any of the common gastrointestinal adverse side effects  
22 associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance,  
23 NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with  
24 long-term use. Defendants promoted Bextra as a safe and effective alternative that would not  
25 have the same deleterious and painful impact on the gut, but that would be just as effective, if not  
26 more so, for pain relief.

27           63.     Bextra possessed dangerous and concealed or undisclosed side effects,  
28 including the increased risk of serious cardiovascular events, such as heart attacks, unstable

1 angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as  
2 strokes. In addition, Bextra was no more effective than traditional and less expensive NSAIDs  
3 and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal  
4 bleeding. Defendants chose not to warn about these risks and dangers.

5           64. Defendants knew of these risks before the U.S. Food and Drug  
6 Administration (the "FDA") approved Bextra for sale on November 16, 2001, but Defendants  
7 ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied  
8 inefficacy in its promotion, advertising, marketing, and sale of Bextra. Defendants' omission,  
9 suppression, and concealment of this important information enabled Bextra to be sold to, and  
10 purchased, or paid for by, the Consumers at a grossly inflated price.

11           65. Consequently, Bextra captured a large market share of anti-inflammatory  
12 drugs prescribed for and used by patients. In 2004 alone sales of Bextra exceeded \$1 billion,  
13 despite the significantly higher cost of Bextra as compared to other pain relievers in the same  
14 family of drugs.

15           66. Because Defendants engaged in a promotional and marketing campaign  
16 that featured an advertising blitz directly targeted to consumers, that touted Bextra as a safer drug  
17 than other drugs in its class, while uniformly failing to disclose the health risks of Bextra,  
18 Defendants were able to justify pricing Bextra significantly higher than the cost of generic  
19 aspirin. In reality, that price inflation was not justified. Had Defendants disclosed the truth about  
20 Bextra, Defendants would not and could not have reaped the billions of dollars in Bextra sales  
21 that were achieved as a direct result of the concealment, omission, suppression, and obfuscation  
22 of the truth.

23           67. Instead of revealing the risks of Bextra, Defendants intentionally  
24 downplayed the risks from Bextra in news releases when Bextra's safety was challenged for the  
25 first time in the mainstream media. *See e.g.*, Nov. 10, 2004 Pfizer News Release ("Pfizer Inc.  
26 said a Named Plaintiff's Home District Times article published today draws unsubstantiated  
27 conclusions about the cardiovascular safety of its Cox-2 medicine Bextra . . ."). Defendants  
28 similarly had earlier downplayed the risks in communicating to healthcare providers misleadingly

1 stating that “available clinical information for Bextra suggests there is no increased risk of  
2 cardiovascular thromboembolic events in people treated for osteoarthritis (OA) and rheumatoid  
3 arthritis (RA)” Oct. 15, 2004 *Pfizer News Release*. Defendants intentionally, deliberately,  
4 knowingly, and actively concealed, omitted, suppressed, and obfuscated important and material  
5 information regarding the risks, dangers, defects, and disadvantages of Bextra from Plaintiff, the  
6 public, the medical community, and the regulators. This concealment and omission was  
7 deliberate, knowing, active, and uniform, was intended to induce and maximize sales and  
8 purchases of Bextra, and prevented Plaintiff from obtaining all the material information that  
9 would be important to their decisions as reasonable persons to purchase, pay for, and/or use  
10 Bextra.

11           68. Defendants’ systematic, active, knowing, deliberate, and uniform  
12 concealment, omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or  
13 use Bextra; and caused Plaintiff’s losses and damages as asserted herein.

14           69. Had Defendants done adequate testing prior to approval and “market  
15 launch,” Pharmacia’s scientific data would have revealed significant increases in stroke and  
16 myocardial infarction amongst the intended population of Bextra consumers. Adequate testing  
17 would have shown that Bextra possessed serious side effects. Defendants should have taken  
18 appropriate measures to ensure that their defectively designed product would not be placed in the  
19 stream of commerce and/or should have provided full and proper warnings accurately and fully  
20 reflecting the scope and severity of symptoms of those side effects should have been made.

21           70. In fact, post-market approval data did reveal increased risks of clotting,  
22 stroke and myocardial infarction, but this information was intentionally suppressed by Defendants  
23 in order for them to gain significant profits from continued Bextra sales.

24           71. Defendants’ failure to conduct adequate testing and/or additional testing  
25 prior to “market launch” was based upon their desire to generate maximum financial gains for  
26 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2  
27 inhibitor market.  
28



1           72. At the time Defendants manufactured, advertising, and distributed Bextra  
2 to consumers, Defendants intentionally or recklessly ignored and/or withheld information  
3 regarding the increased risks of hypertension, stroke and/or myocardial infarctions because  
4 Defendants knew that if such increased risks were disclosed, consumers would not purchase  
5 Bextra, but instead would purchase other cheaper and safer NSAID drugs.

6           73. At all times relevant herein, Defendants engaged in a marketing campaign  
7 with the intent that consumers would perceive Bextra as a better drug than its competitors and,  
8 therefore, purchase Bextra.

9                                   **CLAIMS FOR RELIEF**

10                           **FIRST CLAIM FOR RELIEF:**

11                                   **Negligence**

12           74. Plaintiff incorporates by reference all of the paragraphs of this Complaint  
13 as if fully set forth herein.

14           75. Defendants owed Plaintiff a duty to exercise reasonable care when  
15 designing, manufacturing, marketing, advertising, distributing, and selling Bextra. This duty  
16 included the duty not to introduce a pharmaceutical drug, such as Bextra, into the stream of  
17 commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side  
18 effects.

19           76. At all relevant times to this action, Defendants owed a duty to properly  
20 warn Plaintiff and the Public of the risks, dangers and adverse side effects of their pharmaceutical  
21 drug Bextra.

22           77. Defendants breached their duties by failing to exercise ordinary care in the  
23 preparation, design, research, testing, development, manufacturing, inspection, labeling,  
24 marketing, promotion, advertising and selling of Bextra, including:

25                   a. failing to use due care in the preparation and development of Bextra  
26 to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

27                   b. failing to use due care in the design of Bextra to prevent the  
28 aforementioned risk of injuries to individuals when the drugs were ingested;

- c. failing to conduct adequate pre-clinical testing and research to determine the safety of Bextra;
- d. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Bextra;
- e. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, consumers, the medical community, and the FDA;
- f. failing to accompany Bextra with proper warnings regarding all possible adverse side effects associated with the use of Bextra;
- g. failing to use due care in the manufacture, inspection, and labeling of Bextra to prevent the aforementioned risk of injuries to individuals who used Bextra;
- h. failing to use due care in the promotion of Bextra to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- i. failing to use due care in the sale and marketing of Bextra to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- j. failing to use due care in the selling of Bextra to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- k. failing to provide adequate and accurate training and information to the sales representatives who sold Bextra;
- l. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of Bextra; and
- m. being otherwise reckless, careless and/or negligent.

78. Despite the fact that Defendants knew or should have known that Bextra caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, Defendants continued to promote and market Bextra to consumers, including Plaintiff, when safer and more effective methods of pain relief were available.

79. Defendants were, or should have been, had they exercised reasonable care, in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless,

1 they continued to market their products by providing false and misleading information with  
2 regard to the safety and efficacy of Bextra.

3 80. Defendants knew or should have known that consumers such as Plaintiff  
4 would foreseeably suffer injury as a result of their failure to exercise ordinary care as described  
5 above.

6 81. As a result of Defendants' actions, Plaintiff, and the Plaintiff's prescribing  
7 physicians were unaware, and could not have reasonably known or have learned through  
8 reasonable diligence, that the Plaintiff had been exposed to the risks identified in this complaint,  
9 and that those risks were the direct and proximate result of Defendants' acts, omissions, and  
10 misrepresentations.

11 82. Defendants were, or should have been had they exercised reasonable care,  
12 in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless,  
13 they continued to market their products by providing false and misleading information with  
14 regard to the safety and efficacy of Bextra.

15 83. Defendants knew or should have known that consumers such as Plaintiff  
16 would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described  
17 above.

18 84. As a direct and proximate consequence of Defendants' acts, omissions, and  
19 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has  
20 required and will require healthcare and services; has incurred and will continue to incur medical  
21 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the  
22 future; has suffered and will continue to suffer mental anguish, diminished capacity for the  
23 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
24 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's  
25 direct medical losses and costs include care for hospitalization, physician care, monitoring,  
26 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

27 85. Defendants' conduct was committed with knowing, conscious, wanton,  
28

1 willful, and deliberate disregard for the value of human life and the rights and safety of  
2 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so  
3 as to punish Defendants and deter them from similar conduct in the future.

4 WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
5 compensatory damages, and exemplary and punitive damages together with interest, the costs of  
6 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

7 **SECOND CLAIM FOR RELIEF:**  
8 **Strict Liability – Defective Design and Failure to Warn**

9 86. Plaintiff incorporates by reference all previous paragraphs of this  
10 Complaint as if fully set forth herein and further alleged as follows:

11 87. At all times relevant to this action, Defendants were suppliers of Bextra,  
12 placing the drug into the stream of commerce. Bextra was expected to and did reach Plaintiff  
13 without substantial change in the condition in which it was manufactured and sold.

14 88. Bextra was unsafe for normal or reasonably anticipated use.

15 89. Bextra was defective in design or formulation because when it left the  
16 hands of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous  
17 than an ordinary consumer would expect. Bextra was also defective and unreasonably dangerous  
18 in that the foreseeable risk of injuries from Bextra exceeded the benefits associated with the  
19 design and/or formulation of the product.

20 90. At all times material hereto, Bextra was sold, marketed, distributed,  
21 supplied, manufactured and/or promoted by the Defendant, in a defective and unreasonably  
22 dangerous condition at the time it was placed in the stream of commerce in ways which include,  
23 but are not limited to, one or more of the following particulars.

24 91. When placed in the stream of commerce, the drug contained unreasonably  
25 dangerous design defects and was not reasonably safe as intended to be used, subjecting  
26 Plaintiff's Plaintiff to risks which exceeded the benefits of the drug:  
27  
28



1                   a.       When placed in the stream of commerce, it was defective in design  
2 and formulation, making use of the drug more dangerous than an ordinary consumer would  
3 expect and more dangerous than other similar drugs;

4                   b.       The drug was insufficiently tested;

5                   c.       The drug caused harmful side effects which outweighed any  
6 potential utility;

7                   d.       The drug was not accompanied by adequate instructions and/or  
8 warnings to fully apprise the consumers, including the Plaintiff, of the full nature or extent of the  
9 risks and side effects associated with use, thereby rendering Defendants liable to the Plaintiff and  
10 Plaintiff, individually and collectively, pursuant to the Restatement (Second) of Torts, § 402A, as  
11 adopted by the Named Plaintiff's Home District Courts.

12               92.       The drug was defective and unreasonably dangerous when it left the  
13 possession of the Defendants in that it contained warnings insufficient to alert consumers,  
14 including the Plaintiff, to the dangerous risks and reactions associated with the drug, including,  
15 but not limited to, increased risk of cardiovascular events, and other serious and life threatening  
16 side affects.

17               93.       The Plaintiff could not have discovered any defect in the drug through the  
18 exercise of care.

19               94.       Defendants, as manufacturers of a prescription drug, are held to the level of  
20 knowledge of an expert in the field.

21               95.       Bextra as manufactured and supplied by Defendants was also defective due  
22 to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate  
23 reporting regarding the results of the clinical trials, testing and study. Defendants failed to  
24 perform adequate testing before exposing Plaintiff to the medication, testing which would have  
25 shown that Bextra had the potential to cause serious side effects including strokes like that which  
26 affected Plaintiff.

27               96.       Bextra as manufactured and supplied by Defendants was defective due to  
28 inadequate post-marketing warnings or instructions because, after Defendants knew or should

1 have known of the risk of injuries from Bextra, they failed to provide adequate warnings to the  
2 medical community and the consumers, to whom they were directly marketing and advertising  
3 Bextra; and, further, it continued to affirmatively promote Bextra as safe and effective.

4 97. Bextra was manufactured, distributed, tested, sold, marketed, advertised  
5 and promoted defectively by Defendants, and as a direct and proximate cause of Defendants'  
6 defective design of Bextra, Plaintiff used Bextra rather than other safer and cheaper NSAIDs. As  
7 a result, Plaintiff suffered the personal injuries described above.

8 98. Information given by Defendants to the medical community and to the  
9 consumers concerning the safety and efficacy of Bextra, especially the information contained in  
10 the advertising and promotional materials, did not accurately reflect the potential side effects of  
11 Bextra.

12 99. Defendants had a continuing duty to warn the Plaintiff of the dangers  
13 associated with the drug.

14 100. Had adequate warnings and instructions been provided, Plaintiff would not  
15 have taken Bextra, and would not have been at risk of the harmful side effects described herein.

16 101. Defendants acted with conscious and deliberate disregard of the  
17 foreseeable harm caused by Bextra.

18 102. Defendants were, or should have been had they exercised reasonable care,  
19 in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless,  
20 they continued to market their products by providing false and misleading information with  
21 regard to the safety and efficacy of Bextra.

22 103. Defendants knew or should have known that consumers such as Plaintiff  
23 would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described  
24 above.

25 104. As a direct and proximate consequence of Defendants' acts, omissions, and  
26 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has  
27 required and will require healthcare and services; has incurred and will continue to incur medical  
28 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the

1 future; has suffered and will continue to suffer mental anguish, diminished capacity for the  
2 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
3 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's  
4 direct medical losses and costs include care for hospitalization, physician care, monitoring,  
5 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

6 105. Defendants' conduct was committed with knowing, conscious, wanton,  
7 willful, and deliberate disregard for the value of human life and the rights and safety of  
8 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so  
9 as to punish Defendants and deter them from similar conduct in the future.

10 WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
11 compensatory damages, and exemplary and punitive damages together with interest, the costs of  
12 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

13 **THIRD CLAIM FOR RELIEF:**  
14 **Breach of Express Warranty**

15 106. Plaintiff incorporates by reference all of the paragraphs of this Complaint  
16 as if fully set forth herein.

17 107. Defendants expressly represented to Plaintiff and other consumers and the  
18 medical community that Bextra was safe and fit for its intended purposes, that it was of  
19 merchantable quality, that it did not produce any dangerous side effects, particularly any  
20 unwarned-of side effects, and that it was adequately tested.

21 108. These warranties came in the form of:

22 a. Defendants' public written and verbal assurances of the safety and  
23 efficacy of Bextra;

24 b. Press releases, interviews and dissemination via the media of  
25 promotional information, the sole purpose of which was to create an increased demand for  
26 Bextra, which failed to warn of the risk of injuries inherent to the ingestion of Bextra, especially  
27 to the long-term ingestion of Bextra;  
28

1 c. Verbal and written assurances made by Defendants regarding  
2 Bextra and downplaying the risk of injuries associated with the drug;

3 d. False and misleading written information, supplied by Defendants,  
4 and published in the Physician's Desk Reference on an annual basis, upon which physicians  
5 relied in prescribing Bextra during the period of Plaintiff's ingestion of Bextra, and;

6 e. advertisements.

7 109. The documents referred to above were created by and at the direction of  
8 Defendants.

9 110. Defendants knew or had reason to know that Bextra did not conform to  
10 these express representations in that Bextra is neither as safe nor as effective as represented, and  
11 that Bextra produces serious adverse side effects.

12 111. Bextra did not and does not conform to Defendants' express  
13 representations because it is not safe, has numerous and serious side effects, including unwarned-  
14 of side effects, and causes severe and permanent injuries.

15 112. Plaintiff, other consumers, and the medical community relied upon  
16 Defendants' express warranties.

17 113. Defendants were, or should have been had they exercised reasonable care,  
18 in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless,  
19 they continued to market their products by providing false and misleading information with  
20 regard to the safety and efficacy of Bextra.

21 114. Defendants knew or should have known that consumers such as Plaintiff  
22 would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described  
23 above.

24 115. As a direct and proximate consequence of Defendants' acts, omissions, and  
25 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has  
26 required and will require healthcare and services; has incurred and will continue to incur medical  
27 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the  
28 future; has suffered and will continue to suffer mental anguish, diminished capacity for the



1 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
2 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's  
3 direct medical losses and costs include care for hospitalization, physician care, monitoring,  
4 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

5 116. Defendants' conduct was committed with knowing, conscious, wanton,  
6 willful, and deliberate disregard for the value of human life and the rights and safety of  
7 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so  
8 as to punish Defendants and deter them from similar conduct in the future.

9 WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
10 compensatory damages, and exemplary and punitive damages together with interest, the costs of  
11 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

12 **FOURTH CLAIM FOR RELIEF:**  
13 **Breach of Implied Warranty**

14 117. Plaintiff incorporates by reference all of the paragraphs of this Complaint  
15 as if fully set forth herein.

16 118. Defendants manufactured, distributed, advertised, promoted, and sold  
17 Bextra.

18 119. At all relevant times, Defendants knew of the use for which Bextra was  
19 intended and impliedly warranted the product to be of merchantable quality and safe and fit for  
20 such use.

21 120. Defendants were aware that consumers, including Plaintiff, would use  
22 Bextra for treatment of pain and inflammation and for other purposes.

23 121. Plaintiff and the medical community reasonably relied upon Defendants'  
24 judgment and expertise to only sell them or allow them to prescribe Bextra only if it was indeed  
25 of merchantable quality and safe and fit for its intended use. Consumers, including Plaintiff, and  
26 the medical community, reasonably relied upon Defendants' implied warranty for Bextra.

27 122. Bextra reached consumers, including Plaintiff, without substantial change  
28 in the condition in which it was manufactured and sold by Defendants.

123. Defendants breached their implied warranty to consumers, including Plaintiff; Bextra was not of merchantable quality or safe and fit for its intended use.

124. Defendants were, or should have been had they exercised reasonable care, in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless, they continued to market their products by providing false and misleading information with regard to the safety and efficacy of Bextra.

125. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described above.

126. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

127. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

**FIFTH CLAIM FOR RELIEF:**  
**Fraudulent Misrepresentation & Concealment**

128. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

129. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of Bextra, and their intentional dissemination of promotional and marketing information about Bextra for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about Bextra's risks and harms to doctors and consumers.

130. Defendants made fraudulent affirmative misrepresentations with respect to Bextra in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Bextra had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b. Defendants represented that Bextra was safer than other alternative medications.

131. Defendants made affirmative misrepresentations; and fraudulently, intentionally and/or recklessly concealed material adverse information regarding the safety and effectiveness of Bextra.

132. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or had reason to know that Bextra had defects and was unreasonably dangerous and was not what Defendants had represented to the medical community, the FDA and the consuming public, including Plaintiff.

133. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of Bextra including, but not limited to, the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants'

1 purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the  
2 serious nature of the risks associated with the use of Bextra in order to increase its sales.

3 134. The representations and concealment were undertaken by Defendants with  
4 an intent that doctors and patients, including Plaintiff, rely upon them.

5 135. Defendants' representations and concealments were undertaken with the  
6 intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to  
7 induce and encourage the sale of Bextra.

8 136. Defendants' fraudulent representations evinced their callous, reckless,  
9 willful, and depraved indifference to the health, safety, and welfare of consumers, including  
10 Plaintiff.

11 137. Plaintiff's physician and Plaintiff relied on and were induced by  
12 Defendants' misrepresentations, omissions, and/or active concealment of the dangers of Bextra in  
13 selecting Bextra treatment.

14 138. Plaintiff and the treating medical community did not know that the  
15 representations were false and were justified in relying upon Defendants' representations.

16 139. Had Plaintiff been aware of the increased risk of side effects associated  
17 with Bextra and the relative efficacy of Bextra compared with other readily available  
18 medications, Plaintiff would not have taken Bextra.

19 140. Defendants were, or should have been had they exercised reasonable care,  
20 in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless,  
21 they continued to market their products by providing false and misleading information with  
22 regard to the safety and efficacy of Bextra.

23 141. Defendants knew or should have known that consumers such as Plaintiff  
24 would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described  
25 above.

26 142. As a direct and proximate consequence of Defendants' acts, omissions, and  
27 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has  
28 required and will require healthcare and services; has incurred and will continue to incur medical



1 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the  
2 future; has suffered and will continue to suffer mental anguish, diminished capacity for the  
3 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
4 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's  
5 direct medical losses and costs include care for hospitalization, physician care, monitoring,  
6 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

7 143. Defendants' conduct was committed with knowing, conscious, wanton,  
8 willful, and deliberate disregard for the value of human life and the rights and safety of  
9 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so  
10 as to punish Defendants and deter them from similar conduct in the future.

11 WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
12 compensatory damages, and exemplary and punitive damages together with interest, the costs of  
13 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

14 **SIXTH CLAIM FOR RELIEF**  
15 **(Unjust Enrichment)**

16 144. Plaintiff incorporates by reference all previous paragraphs of this  
17 Complaint as if fully set forth herein.

18 145. At all times relevant to this action, Defendants were the manufacturers,  
19 sellers, and/or suppliers of Bextra.

20 146. Plaintiff paid for Bextra for the purpose of managing her pain safely and  
21 effectively.

22 147. Defendants have accepted payment from Plaintiff for the purchase of  
23 Bextra.

24 148. Plaintiff did not receive the safe and effective pharmaceutical product for  
25 which Plaintiff paid.

26 149. It is inequitable and unjust for Defendants to retain this money because the  
27 Plaintiff did not in fact receive the product Defendant represented Bextra to be.

28 WHEREFORE, Plaintiff demands judgment against Defendants and seeks

1 equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court  
2 deems just and proper.

3 **PRAYER FOR RELIEF**

4 WHEREFORE, Plaintiff requests the following relief:

- 5 1. General damages in excess of the jurisdictional amount of this Court;  
6 2. Consequential damages;  
7 3. Disgorgement of profits;  
8 4. Restitution;  
9 5. Punitive and exemplary damages;  
10 6. Pre-judgment and post-judgment interest as provided by law;  
11 7. Recovery of Plaintiff's costs including, but not limited to, discretionary  
12 Court costs of these causes, and those costs available under the law, as well as expert fees and  
13 attorneys' fees and expenses, and costs of this action; and  
14 8. Such other and further relief as the Court deems just and proper.

15  
16 Dated: February 15, 2008

Respectfully submitted,

17  
18 By: 

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26  
27 Attorneys for Plaintiff  
28

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: February 15, 2008

Respectfully submitted,

By: 

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